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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,078	03/24/2004	Mark Tsonton	END-5293	7086

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EXAMINER	
ROY, ANURADHA	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,078	TSONTON ET AL.	
	Examiner	Art Unit	
	Anuradha Roy	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

The previous claims objections are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1-4 & 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (US Publication No. 2003/0028094) in view of Huitema et al. (US Patent No. 6,626,849).

Regarding claim 1, Kumar et al. discloses a biopsy device suitable for use with a magnetic resonance imaging machine, said device comprising an elongated needle (1810) for receiving tissue therethrough, the needle comprising: a distal needle segment (1811) comprising a tissue receiving port (1812), the distal needle segment formed of a first material [0045] that does not interfere with MRI imaging of a portion of the distal needle segment associated with the tissue receiving port; a proximal needle segment (1890 & 1820) disposed proximally of the tissue receiving port, the proximal needle segment formed at least in part of a second material different from said first material [0188]. However, Kumar et al. does not distinctly that the proximal needle segment and the distal needle segment are at least one substantially continuous lumen, wherein the proximal needle segment and the distal needle segment are longitudinally joined along

a common axis. Huitema et al., however, discloses a device wherein the distal and proximal needle segments are at least one substantially continuous lumen (Figure 3: 31 & 33), wherein the proximal needle segment and the distal needle segment are longitudinally joined along a common axis (Column 4, lines 12-14). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Huitema et al. to have a substantially continuous lumen with Kumar et al. in order to facilitate the movement of the extracted tissue from the distal to the proximal end (Column 4, lines 31-43).

Regarding claims 2, 3, & 16 –18, Kumar discloses a biopsy device suitable for use with a magnetic resonance imaging machine and comprising: a distal needle segment (1811) comprising a tissue receiving port (1812) communicating with a distal cutter lumen portion, the distal needle segment formed of a first material [0045]; and a proximal needle segment (1890 & 1820) formed at least in part of a metal [0188], the proximal needle segment comprising a proximal cutter lumen portion (Figure 18 & 19), and wherein said metal is spaced proximally at least about 0.5 inch from a proximal edge of said tissue receiving port [0079]. Kumar, however, does not teach of the first material being a non-metallic material. However, Huitema et al. teaches of a non-metallic and nonmagnetic material (Column 4, lines 25-31) for the distal region of the needle. It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Huitema et al. to utilize a non-metallic and non-magnetic material on the needle with Kumar et al. in order to prevent an obscured image of the lesion by the needle.

> "The image of the lesion will show the metal probe, and this is problematic because the image of the probe can obscure the image of the lesion. Therefore, there has been a desire to have a generally non-metallic biopsy probe of the type described above." (Column 2, lines 59-63)

Furthermore, regarding claims 16-18, Kumar et al. does not distinctly that the proximal needle segment and the distal needle segment are at least one substantially continuous lumen, wherein the proximal needle segment and the distal needle segment are longitudinally joined along a common axis. Huitema et al., however, discloses a device wherein the distal and proximal needle segments are at least one substantially continuous lumen (Figure 3: 31 & 33), wherein the proximal needle segment and the distal needle segment are longitudinally joined along a common axis (Column 4, lines 12-14). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Huitema et al. to have a substantially continuous lumen with Kumar et al. in order to facilitate the movement of the extracted tissue from the distal to the proximal end (Column 4, lines 31-43).

Regarding claim 4, Huitema et al. further discloses a distal needle segment, wherein the first material comprises a liquid crystal polymer (Column 4, lines 25-31).

With regard to claims 6-8, Kumar et al. discloses a proximal needle segment, wherein the second material comprises a metal and is non-magnetic [0186] and is selected from the group comprising aluminum, aluminum alloys, stainless steel, titanium, titanium alloys, and combinations thereof [0186]. Examiner contends wire is a form of metal according to the definition found in the Webster dictionary online.

With regard to claims 9-11, Huitema et al. discloses a device further comprising a distal piercing tip (Figure 1 & 60) disposed distal of the tissue receiving port, wherein the

distal piercing tip comprises a non-metallic material and is selected from the group comprising ceramics and glasses (Column 7, lines 30-34).

In regards to claim 12, Huitema et al. discloses a device, wherein the proximal needle segment (33) and the distal needle segment provide a continuous, smooth cutter lumen (32).

In regards to claim 13, Huitema et al. discloses a device, wherein the proximal needle segment and the distal needle segment provide a continuous vacuum lumen (34).

In regards to claim 14, Huitema et al. discloses a device, wherein the needle comprises at least passage (36) extending from the vacuum lumen to an outer surface of the needle.

In regards to claim 15, Huitema et al. discloses a device, wherein the distal needle segment comprises a plurality of passages (Figure 4 & 23) extending from the vacuum lumen to the outer surface of the needle.

Regarding claim 19, Kumar et al. discloses a biopsy device suitable for use with a magnetic resonance imaging machine, said device comprising an elongated needle (1810) for receiving tissue therethrough, the needle comprising: a distal needle segment (1811) having a tissue receiving port (1812) communicating with a distal cutter lumen segment, wherein the distal needle segment has a proximal end; a metallic proximal needle segment (1890 & 1820) disposed proximally of the tissue receiving port, wherein the metallic proximal needle segment provides a proximal cutter lumen segment

communicating with the distal cutter lumen segment, wherein the proximal needle segment has a distal end (Figure 18 & 19), wherein the distal end of the proximal needle segment is positioned distally of the proximal end of the distal needle segment (Figure 18 & 19). Kumar, however, does not teach of the first material being a non-metallic material. However, Huitema et al. teaches of a non-metallic and nonmagnetic material (Column 4, lines 25-31) for the distal region of the needle. It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Huitema et al. to utilize a non-metallic and non-magnetic material on the needle with Kumar et al. in order to prevent an obscured image of the lesion by the needle.

> "The image of the lesion will show the metal probe, and this is problematic because the image of the probe can obscure the image of the lesion. Therefore, there has been a desire to have a generally non-metallic biopsy probe of the type described above." (Column 2, lines 59-63)

With regard to claim 20, Huitema et al. discloses a device, wherein the distal needle segment comprises at least a portion of a vacuum lumen (Figure 4 & 34).

Additional Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. in view of Sapatova et al. (US Publication No. 2003/0203140).

Kumar et al. discloses the aforementioned element of a biopsy device. Kumar et

al., however, does not directly disclose a melt flow index of at least about 15 grams/minute. However, Sapatova et al. teaches of a melt flow index of at least about 15 grams/minute ([0015] & [0047]). It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Sapatova et al. to have a melt flow index of at least 15 grams/minute with Kumar et al. in order to allow for the "implementation of multi-cavitation tools, and a commensurate increase in productivity" [0047].

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is 571-272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 9:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR

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